

CASEREVIEW

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Notice of Independent Review Decision

[Date notice sent to all parties]: April 30, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Euflexxa Injections x 3 to Left Ankle

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This physician is a Board Certified Orthopedic Surgeon with over 13 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on xx/xx/xx. On December 6, 2011, the claimant underwent a left ankle mini-arthrotomy with extension into a larger arthrotomy, excision of loose bodies from joint, osteotomy of the talus for a very large arthritic spur on the anterior aspect of the talus, limited osteotomy of some spurring on the tibia anteriorly, tendoachilleing lengthening.

On October 31, 2014, the claimant presented with no change in his symptoms. He stated he noticed more stiffness and dull pain regularly. He received a cortisone injection at his last visit that was not effective. It was also noted that previous visco supplementation Euflexxa was effective. He is taking 200 mg ibuprofen 2-3 x daily and Norco. On examination there was restricted dorsiflexion with good plantar flexion. He had limited inversion and eversion of the ankle. He had 1+ effusion in his ankle joint. He also had tenderness to palpation over the medial and lateral joint line. Motor, sensation and circulation were intact. There

was no excessive warmth and no evidence of infection. Plan: Continue with low impact activities. Elevate extremely when at rest. Continue home exercise. Continue ice treatment. Continue with current medications. Will resubmit for Euflexxa series for left ankle.

On February 25, 2015, the claimant presented who reported on physical examination of the left ankle there was limited inversion and eversion with good dorsiflexion and plantar flexion. He did have tenderness to palpation at the anterior medial and lateral joint lines. He had no effusion present. There was quite a bit of crepitus noted with range of motion of the ankle. He had stable anterior drawer. He had a negative calcaneal squeeze. He was measured to be 5'8" and weighs 330 pounds. His pain was rated 5-6 out of 10. X-rays taken at previous visit demonstrated osteoarthritis of the ankle joint that is post-traumatic in nature. Assessment: post-traumatic osteoarthritis of the left ankle. Plan: Continue to work on his previous Euflexxa authorization for the ankle which he stated did help him quite a bit in the past. Recommended a repeat cortisone injection in his left ankle which they performed under ultrasound guidance without difficulty. Norco prescription was refilled.

On March 26, 2015, UR. Rationale for Denial: The request does not meet evidence based guidelines. There is ankle arthritis. The claimant has BMI of 50. There was no significant improvement with prior injection. The results of this injection have not been shown to be effective in changing the natural history of the arthritis. Based on a lack of significant improvement in pain and function with the prior injection, the request does not meet evidence based guidelines.

On April 6, 2015, UR. Rationale for Denial: Guideline criteria have not been met as this request has not been proven in large volume high quality medical literature to be an effective treatment. In addition, there is no documentation noting exceptional indications for this request in this patient's clinical scenario. Therefore, this request is not medically reasonable or necessary at this time.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The Official Disability Guidelines (ODG) does not recommend hyaluronic acid injections for ankle arthritis. The literature does not support the effectiveness of these injections in the ankle. The injections are not a cure for arthritis.

The patient has not demonstrated long-term improvement in his ankle arthritis with previous Euflexxa injections. He is morbidly obese and is currently taking narcotics for his ankle pain. Injections will not provide this patient with a permanent solution.

Euflexxa Injections x 3 to Left Ankle are not recommended for this patient.

PER ODG:

Hyaluronic acid	Not recommended, based on recent research in the ankle, plus several
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injections

recent quality studies in the knee showing that the magnitude of improvement appears modest at best. Was formerly under study as an option for ankle osteoarthritis. Hyaluronic acids are naturally occurring substances in the body's connective tissues that cushion and lubricate the joints. Intra-articular injection of hyaluronic acid may decrease symptoms of osteoarthritis of the knee, and possibly the ankle. This double blind, randomized, controlled study examined the safety and efficacy of intraarticular sodium hyaluronate (Hyalgan) in the treatment of pain associated with ankle osteoarthritis (OA), and concluded that this may be a safe and effective option for pain associated with ankle OA, although larger studies are needed. ([Cohen, 2008](#)) This clinical trial suggested that viscosupplementation combined with arthroscopy may be more beneficial than arthroscopy alone. ([Carpenter, 2008](#)) The goal of this study was to determine whether hyaluronic acid (HA) or exercise therapy can improve functional parameters in patients with osteoarthritis (OA) of the ankle, and both HA injections and exercise therapy provided similar functional improvement. However, larger trials with longer follow-up are necessary for more definite conclusions. ([Karatosun, 2008](#)) According to this systematic review of treatment for ankle sprains, therapeutic hyaluronic acid injections in the ankle may have a role in expediting return to sport after ankle sprain, but evidence is limited. ([Seah, 2011](#)) See the [Knee Chapter](#) for more information.

Recent research: While intra-articular injections of hyaluronic acid are potentially useful to treat ankle osteoarthritis, their effectiveness has not been proven. This RCT comparing hyaluronic acid with placebo for ankle osteoarthritis concluded that hyaluronic acid is not superior to saline solution injection. ([DeGroot, 2012](#))

Hyaluronic acid or Hylan for the Ankle is Not Recommended by ODG.

Patient selection criteria for ankle hyaluronic acid injections if provider & payor agree to perform anyway:

A series of three to five intra-articular injections of Hyaluronic acid (or just three injections of Hylan) in the target ankle with an interval of one week between injections.

Indicated for patients who:

- Experience significantly symptomatic osteoarthritis but have not responded adequately to standard nonpharmacologic and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications).
- Are not candidates for total ankle replacement or who have failed previous ankle surgery for their arthritis, such as arthroscopic debridement.
- Repeat series of injections: If relief for 6-9 months and symptoms recur, may be reasonable to do another series. Recommend no more than 3 series of injections over a 5-year period, because effectiveness may decline, this is not a cure for arthritis, but only provides comfort and functional improvement.

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR
OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL &
ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY
GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR
GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW
BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN
ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE &
PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE
(PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME
FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**